Not for Publication

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA *ex rel.* CHARLES L. BENNETT, **Plaintiff-Relator,** **v.** **BAYER CORPORATION, *et al.*** **Defendants.**	**Civil Action No. 17-4188 (ES) (JBC)** **OPINION**

SALAS, DISTRICT JUDGE

In this qui tam action, Relator Charles L. Bennett sues Defendants Bayer Corporation and Merck & Co., Inc. (together, "Bayer"), and Defendants Johnson & Johnson, Johnson & Johnson Pharmaceutical Research & Development, and Ortho-McNeil-Janssen Pharmaceuticals (together, "J&J"). (D.E. No. 6, Amended Complaint ("Am. Compl.")). Relator claims that Bayer and J&J violated the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.*, and similar state laws by misbranding two fluoroquinolones ("FQs"), thereby causing physicians to prescribe the drugs and seek reimbursement from government programs such as Medicare and Medicaid. (Am. Compl. ¶¶ 3–9). Bayer and J&J separately move to dismiss the Amended Complaint. (D.E. Nos. 38 & 41). Having considered the parties' submissions, the Court decides this matter without oral argument. *See* Fed. R. Civ. P. 78(b); L. Civ. R. 78.1(b). For the reasons set forth below, Defendants' motions are GRANTED. The Amended Complaint is dismissed *without prejudice*.

I. BACKGROUND

A. FQs

An FQ is an antibiotic that treats certain bacterial infections. Cipro and Levaquin are FQs. Cipro is manufactured by Bayer and is the brand name for ciprofloxacin. (Am. Compl. ¶¶ 4–5). Levaquin is manufactured by J&J and is the brand name for levofloxacin. (*Id.* ¶¶ 28 & 46). Both Cipro and Levaquin are part of billion-dollar industries. (*Id.* ¶¶ 45 & 47).

B. Misbranding Allegations

Relator claims that Cipro and Levaquin are misbranded. Specifically, he claims that their labels should disclose warnings that both may cause mitochondrial toxicity; Fluoroquinolone-associated Disability ("FQAD"); serious psychiatric adverse events; increased risk of Carbapenem-Resistant Enterobacteriaceae; and delayed adverse events. (*Id.* ¶¶ 67–89). He also alleges that the labels should explain to patients how to take Cipro and Levaquin, warn patients of the dangers of concomitant use of Levaquin and non-steroidal anti-inflammatory drugs, and warn patients that the clinical trials of Levaquin were flawed. (*Id.* ¶¶ 90–94). He bases these assertions on, among other things, scientific research and analysis that he and others, including Food and Drug Administration ("FDA") officials, conducted.[1] Relator also points to FDA reporting.

C. Research and Analysis and FDA Reporting

First, Relator cites the FDA's pharmacovigilance review of systemic FQ exposure dated April 17, 2013. (*Id.* ¶¶ 7, 51, 57–58 & 67–68). That review was co-authored by FDA official Dr. Deborah Boxwell, and it identified "FQAD by using the FDA's reporting system through which

[1] Among the other research and analysis, outlined *infra*, Relator points to the 2006 discovery of Dr. Sidney Wolfe and others that FQs cause "acute rupture of the Achilles tendon," even "in patients who had only taken as few as 1-2 doses." (Am. Compl. ¶ 48). This discovery caused the FDA to require Defendants to implement labeling changes. (*Id.*). However, Relator's claims do not appear to be based on Dr. Wolfe's research and the subsequent labeling changes.

doctors and patients can file complaints of adverse drug reactions." (*Id.* ¶ 57). According to the review, FQAD exists "in patients who had (1) taken an FQ, including Cipro, as prescribed for uncomplicated sinusitis, bronchitis, and urinary tract infections, (2) suffered adverse reactions affecting 'two or more body systems,' including peripheral nervous system, neuropsychiatric, musculoskeletal, senses, cardiovascular, and/or skin and (3) become disabled for 30 days or more." (*Id.*).

Second, Relator points to the reporting system on which the April 17, 2013 pharmacovigilance review was based. That reporting system is known as "FAERS"—short for "FDA Adverse Events Reporting System." (*Id.* ¶ 101). FDA regulations, Relator asserts, "require the manufacturer of any approved drug to submit to the FDA any adverse reaction events from an approved drug with[in] a certain time period: 1) An unexpected death within 24 hours; 2) An unexpected adverse event within 15 days; and 3) Any other adverse event on a quarterly basis." (*Id.*). Relator alleges that the FAERS data for Cipro and Levaquin reported a significant number of adverse events—both psychiatric and neurological—that were not reflected on the drugs' labeling. (*Id.* ¶¶ 81–82, 103–04, 113 & 126). The FAERS data also, according to Relator, "clearly document[ed] that Cipro and Levaquin consumption [wa]s associated with FQAD." (*Id.* ¶ 125). Relator alleges that the FAERS data further reported a significant number of deaths and "individuals damaged" after taking Cipro or Levaquin. (*Id.* ¶¶ 123–124).

Third, Relator cites two citizen petitions that he submitted to the FDA, asking the FDA to change the labeling of Cipro and Levaquin. He filed the first petition on June 18, 2014. (*Id.* ¶ 51). In that petition, he informed the FDA of his independent research of patient data—over 200 patients in total—of unlabeled adverse side effects after using an FQ. (*Id.* ¶¶ 50–51). He obtained that data through an independent pharmacovigilance program that he developed called the

Southern Network on Adverse Reactions ("SONAR"). (*Id.*). He also offered his analysis of the April 17, 2013 pharmacovigilance review. (*Id.* ¶ 51). Relator filed the second petition on September 8, 2014. (*Id.*). In that petition, he informed the FDA of additional research and requested the FDA to review FQ labeling due to serious psychiatric adverse events not listed on the current labeling. (*Id.*). While Relator's petitions identified Levaquin, Relator believed that changing the label of one FQ would domino into changing the label of all FQs, including Cipro. (*Id.*). The FDA acknowledged receipt of his petitions approximately six months after the filing of each. (*Id.* ¶ 52).

Fourth, Relator cites his analysis of patient data that he submitted to the FDA on November 5, 2015, at the FDA Joint Meeting of the Antimicrobial Drugs Advisory Committee and Drug Safety and Risk Management Advisory Committee. (*Id.* ¶ 58). Relator's report "described 54 persons with long term FQ-associated toxicity identified by SONAR." (*Id.*). Present at the meeting were nineteen patients, some of whom were part of Relator's research, who testified about the side effects they suffered after taking an FQ. (*Id.* ¶ 59).

Fifth, Relator points to an FDA briefing document for the November 5, 2015 meeting, in which the FDA found there was "an association between oral fluoroquinolone use . . . and the development of FQAD" and that "a description of the constellation of disabling adverse events is not currently described in the fluoroquinolone labels." (*Id.* ¶ 75). The briefing document also, according to Relator, found some patients suffered from delayed adverse events after taking an FQ. (*Id.* ¶ 89).

Sixth, Relator cites his study, published in January or February 2016, that "combined a clinical study of 94 patients with an experiment utilizing C57BL/Mice." (*Id.* ¶ 132; *see also id.* ¶ 62). This "study was the first of its kind," according to Relator. (*Id.* ¶ 56; *see also id.* ¶ 132).

Specifically, over a ten-day period, Relator administered different doses of Cipro to five sets of mice, leaving one group as a control group. (*Id.* ¶ 133). The results showed, among other things, according to Relator, "that mice treated with Cipro had lower grip strengths, reduced balance, and more depressive behaviors when compared with the controls." (*Id.* ¶ 134). And the higher the dose, the more disparate the effect. (*Id.*). For the clinical study of human patients, "93 of the 94 human patients reported FQ-associated effects." (*Id.* ¶ 135). Those patients suffered from "a range of psychiatric effects," including anxiety, depression, insomnia, panic attacks, brain fog and cognitive impairment, depersonalization, suicidal thoughts, psychosis and hallucinations, nightmare and abnormal dreams, impaired memory, emotional outbursts, and paranoia. (*Id.*). Many patients reported side effects not listed on the Cipro label. (*Id.* ¶ 136). This research "revealed significant Cipro toxicity and concluded that the current Cipro labeling is inadequate." (*Id.* ¶ 137).

D. Government Websites

In addition to the above, Relator points to reporting on government websites to support his claim that Cipro and Levaquin are misbranded. Relator cites the website of the Centers for Disease Control and Prevention ("CDC"), in which the CDC advised the risk of Carbapenem-Resistant Enterobacteriaceae after taking an FQ. (*Id.* ¶¶ 87–88 & 114). Relator also cites the FDA's website advising that J&J's clinical trial of Levaquin had been flawed in certain respects. (*Id.* ¶¶ 93–94).

E. Public Efforts

Relator further claims that he took his complaints to the public. He appeared in over 50 television news segments discussing his work and the alleged undisclosed and harmful side effects of FQs, including Cipro and Levaquin. (*Id.* ¶ 53). And he met, in early 2015, with staffers of various United States Senators. (*Id.*).

F. Labeling Changes

Relator alleges that, due to safety concerns for Cipro and Levaquin, the FDA has required Bayer and J&J to change the labels to reflect previously undisclosed side effects. (*Id.* ¶¶ 48 & 63–65, 76–79, 83–86, 127 & 129). The FDA did so in 2006, in May and July 2016, and in July 2018. (*Id.*). Relator also points to a "non-binding FDA vote recommending that Defendants' current labeling is not adequate." (*Id.* ¶ 8). Though it is not clear from the Amended Complaint, Relator appears to allege that the non-binding vote was taken at the November 5, 2015 meeting described *supra*, section I.C. (*Id.* ¶¶ 74 & 110).

However, Relator does not allege that Bayer or J&J failed to comply with any change in labeling. Nor does Relator allege that the FDA ordered Bayer and J&J to change the labels of Cipro and Levaquin to include what Relator now believes ought to have been included.

G. Defendants' Knowledge and Conduct

Relator claims that Bayer and J&J knew or should have known that they should include Relator's proposed additions to their labeling because they had or had access to all of the information outlined above. (*Id.* ¶¶ 106–129). Yet, Relator claims, Bayer and J&J "fought the science." (*Id.* ¶ 9). Relator provides two examples of Bayer and J&J allegedly doing so. First, Relator alleges that "representatives" of "Defendant," who were "accompanied by doctors from Harvard and Canada," were present at the November 5, 2015 FDA Advisory Committee meeting. (*Id.* ¶ 59). At the meeting, they "vehemently denied both the connection between FQs, including Cipro, and the adverse reactions." (*Id.*). They also, Relator alleges, "went as far as to question whether FQAD was a real condition." (*Id.*). "Defendant's representatives insisted the current labeling was sufficient," and they "stood by its product, Cipro." (*Id.*). Second, Relator alleges that, "[w]hen pressed for a statement in response to Relator's Citizen Petitions and news

interviews, Defendants would send letters stating, in some form or another, that Defendant 'stood by the product,' Cipro, and maintained that it was fine as currently labeled." (*Id.* ¶ 54).

H. Theory of Fraud

Relator alleges that Bayer's and J&J's misbranding caused healthcare professionals to inappropriately prescribe Cipro and Levaquin. (*Id.* ¶¶ 4, 9 & 150–53). In turn, those doctors submitted claims to Medicaid and Medicare and, by doing so, falsely certified that Cipro and Levaquin were appropriately prescribed under applicable federal law. (*Id.* ¶¶ 148 & 150–62). That allegedly "tricked Government Programs into providing reimbursements that should not have been provided." (*Id.* ¶ 9; *see also id.* ¶¶ 150–153 & 156). Medicaid and Medicare, according to Relator, "paid out millions of dollars in excess charges based upon false and fraudulent claims" that were "submitted by them, directly or indirectly." (*Id.* ¶ 156).

Accordingly, Relator asserts claims of fraud and conspiracy under the FCA and similar state laws. In particular, Relator alleges that Defendants have violated the FCA by (i) "knowingly presenting, or causing to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval"; (ii) "knowingly making, using or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the United States Government"; and (iii) "by conspiring to defraud the United States Government by getting a false or fraudulent claim allowed or paid." (*Id.* ¶ 166.A–C). On behalf of the United States, he seeks damages, treble damages, and civil penalties. (*Id.* at 66–68).

I. Procedural History

On June 9, 2017, Relator filed this action under seal, naming only Bayer Corporation as a defendant. (D.E. No. 1). On August 10, 2018, Relator filed the operative Amended Complaint.

On September 28, 2020, the United States filed its notice to decline to intervene pursuant to 31 U.S.C. § 3730(b)(4)(B). (D.E. No. 8). Two days later, the matter was restored to the Court's active docket. (D.E. No. 10). The parties agreed to a schedule for Defendants' time to answer or otherwise file a Rule 12 motion. (D.E. No. 20). Defendants separately moved to dismiss the Amended Complaint on March 11, 2021. (D.E. Nos. 38 & 41; *see also* D.E. No. 38-1 ("J&J Mov. Br."); D.E. No. 41-1 ("Bayer Mov. Br.")). Relator filed its opposition brief on April 26, 2021. (D.E. No. 48 ("Opp. Br.")). J&J and Bayer filed their replies on May 10, 2021. (D.E. No. 50 ("J&J Reply"); D.E. No. 51 ("Bayer Reply")).

II. LEGAL STANDARD

In assessing whether a complaint states a cause of action sufficient to survive dismissal under Rule 12(b)(6), the Court accepts "all well-pleaded allegations as true and draw[s] all reasonable inferences in favor of the plaintiff." *City of Cambridge Ret. Sys. v. Altisource Asset Mgmt. Corp.*, 908 F.3d 872, 878 (3d Cir. 2018). "[T]hreadbare recitals of the elements of a cause of action, legal conclusions, and conclusory statements" are all disregarded. *Id.* at 878–79 (quoting *James v. City of Wilkes-Barre*, 700 F.3d 675, 681 (3d Cir. 2012)). The complaint must "contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face," and a claim is facially plausible when the plaintiff "pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Zuber v. Boscov's*, 871 F.3d 255, 258 (3d Cir. 2017) (first quoting *Santiago v. Warminster Twp.*, 629 F.3d 121, 128 (3d Cir. 2010); and then quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)).

Although the Court is generally confined to the allegations in the pleadings in ruling on a motion to dismiss under Rule 12(b)(6), it may, without converting the motion to one for summary judgment, consider a document "*integral to or explicitly relied* upon in the complaint," as well as

"an undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (first quoting *Shaw v. Digital Equip. Corp.*, 82 F.3d 1194, 1220 (1st Cir. 1996); and then quoting *In re Donald J. Trump Casino Sec. Litig.*, 7 F.3d 357, 368 n.9 (3d Cir. 1993)); *see also Lum v. Bank of Am.*, 361 F.3d 217, 221 n.3 (3d Cir. 2004) ("In deciding motions to dismiss pursuant to Rule 12(b)(6), courts generally consider only the allegations in the complaint, exhibits attached to the complaint, matters of public record, and documents that form the basis of a claim.").

Under Rule 9(b), "a party must state with particularity the circumstances constituting fraud or mistake," but "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." In the context of the FCA, a plaintiff need not plead representative samples of fraudulent claims submitted to the Government. *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 155–57 (3d Cir. 2014). Nor must a plaintiff "identify a specific claim for payment at the pleading stage of the case to state a claim for relief." *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 308 (3d Cir. 2011), *abrogated on other grounds as recognized in United States ex rel. Freedom Unlimited, Inc. v. City of Pittsburgh, Pennsylvania*, 728 F. App'x 101, 106 (3d Cir. 2018). Instead, it is enough for a plaintiff to allege the "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Foglia*, 754 F.3d at 156, 158 (quoting *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009)). "Describing a mere opportunity for fraud will not suffice." *Id.* at 158. Thus, "an inference of illegality based on facts that could plausibly have either a legal or illegal explanation [is] insufficient to meet Rule 9(b)'s burden, because a relator must 'establish a "strong inference" that false claims were submitted' and the possibility of a

legitimate explanation undermines the strength of the inference of illegality." *United States v. Omnicare, Inc.*, 903 F.3d 78, 92 (3d Cir. 2018) (quoting *Foglia*, 754 F.3d at 158).

III. DISCUSSION

"Enacted in 1863, the False Claims Act 'was originally aimed principally at stopping the massive frauds perpetrated by large contractors during the Civil War.'" *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 181 (2016) (quoting *United States v. Bornstein*, 423 U.S. 303, 309 (1976)). Today, the FCA is not so limited to its original principal aim, for Congress "has repeatedly amended the Act." *Id.* Still, the FCA's "focus remains on those who present or directly induce the submission of false or fraudulent claims" to the Government for payment. *Id.* To that end, the FCA "enables individuals, known as Relators, to bring enforcement actions, known as *qui tam* actions, on behalf of the United States to recover funds which were fraudulently obtained, and to share in any resulting damages award." *United States ex rel. Dhillon v. Endo Pharms.*, 617 F. App'x 208, 211 (3d Cir. 2015).

Pertinent here, the FCA holds any person liable to the United States who

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> (C) conspires to commit a violation of subparagraph (A), (B) . . . .

31 U.S.C.A. § 3729(a)(1)(A)–(C). An FCA violation "includes four elements: falsity, causation, knowledge, and materiality." *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 487 (3d Cir. 2017).

Even if the FCA's elements are adequately pled, the FCA prohibits some claims based on the "public disclosure bar," *Graham Cty. Soil & Water Conservation Dist. v. United States ex rel.*

Wilson, 559 U.S. 280, 295 (2010), and the "first-to-file bar," *Kellogg Brown & Root Servs., Inc. v. United States ex rel. Carter*, 575 U.S. 650, 662 (2015).

J&J argues that the first-to-file bar prohibits suit against it. Both Bayer and J&J argue that the public disclosure bar requires dismissal and that Relator has failed to sufficiently plead the elements of his FCA claim. Relator opposes each argument. Because the Amended Complaint fails to plausibly plead the elements of an FCA claim, the Court declines to consider the first-to-file bar and the public disclosure bar.[2]

A. Falsity

An actionable claim can be factually or legally false. *Petratos*, 855 F.3d at 486 n.1. "A claim is *factually false* when the claimant misrepresents what goods or services that it provided to the Government[,] and a claim is *legally false* when the claimant knowingly falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for Government payment." *Wilkins*, 659 F.3d at 305 (emphasis added).

"A legally false FCA claim is based on a 'false certification' theory of liability." *Id.* "Such certification may be express or implied." *United States ex rel. Whatley v. Eastwick Coll.*, 657 F. App'x 89, 94 (3d Cir. 2016). An express false certification occurs when the defendant "falsely certif[ies] that it is in compliance with regulations which are prerequisites to Government payment

[2] It appears, however, that neither exception applies on this record. First, the public disclosure bar prohibits relators from bringing claims based on publicly disclosed information that would be sufficient to state an FCA claim. *Omnicare, Inc.*, 903 F.3d at 86 (holding that a district court erred in dismissing a claim under the public disclosure bar because the publicly disclosed information was insufficient to state a claim of fraud under Rule 9(b)). However, as discussed below, Relator cannot maintain a claim of fraud when considering the publicly disclosed information. Second, the first-to-file bar prohibits suit where a relator alleges "all the essential facts of a previously-filed claim." *United States ex rel. LaCorte v. SmithKline Beecham Clinical Lab'ys, Inc.*, 149 F.3d 227, 232 (3d Cir. 1998); *see also United States v. Millenium Lab'ys, Inc.*, 923 F.3d 240, 253 (1st Cir. 2019) (declining to dismiss later-filed claim because the two complaints alleged "different frauds with different mechanisms"). Here, the previously-filed qui tam action is *United States ex rel. Volkhoff v. Jansenn Pharmaceutical*, No. 16-cv-6997 (C.D. Cal.), and it appears the relator there pursued a different theory of fraud based on a different set of essential facts—specifically, "the submission of false claims through an illegal kickback scheme related to several J&J drugs." (Opp. Br. at 24); *see also* Amended Complaint, *Volkhoff*, No. 16-cv-6997 (C.D. Cal. Feb. 16, 2018), D.E. No. 38.

in connection with the claim for payment of federal funds." *Wilkins*, 659 F.3d at 305. In contrast, an implied false certification occurs "when the defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the defendant's noncompliance with a statutory, regulatory, or contractual requirement." *Escobar*, 579 U.S. at 181. "In these circumstances, liability may attach if the omission renders those representations misleading," *id.*, or, put differently, if the representations may be described as "half-truths—representations that state the truth only so far as it goes, while omitting critical qualifying information," *id.* at 188.

In some instances, a relator may pursue a fraudulent inducement theory of liability. "Although the focus of the False Claims Act is on false 'claims,' courts have employed a fraudulent inducement theory to establish liability under the Act for each claim submitted to the government under a contract which was procured by fraud, even in the absence of evidence that the claims were fraudulent in themselves." *United States ex rel. Thomas v. Siemens AG*, 593 F. App'x 139, 143 (3d Cir. 2014). Thus, under a fraudulent inducement theory, even though a claim paid under a contract is "not literally false," the claim may become an actionable false claim if the paid claim arises from an "original fraudulent misrepresentation." *United States ex rel. Brown v. Pfizer, Inc.*, No. 05-6795, 2017 WL 1344365, at *9 (E.D. Pa. Apr. 12, 2017) (quoting *United States ex rel. Longhi v. Lithium Power Techs., Inc.*, 575 F.3d 458, 468 (5th Cir. 2009)).

Bayer and J&J argue that the Amended Complaint should be dismissed because it fails to plead falsity. (J&J Mov. Br. at 19–23; Bayer Mov. Br. at 18–19). Relator's claims, they posit, are premised on an implied false certification theory—that they caused others to submit a claim for reimbursement under Medicaid and Medicare without disclosing that Cipro and Levaquin failed to comply with applicable law. (J&J Mov. Br. at 19; Bayer Mov. Br. at 21). However, they argue

that Relator fails to plead basic facts supporting that theory, such as what laws with which Cipro and Levaquin were non-compliant, how Cipro and Levaquin were non-compliant, who failed to certify such non-compliance, or why certification of non-compliance was necessary. (J&J Mov. Br. at 19–20; Bayer Mov. Br. at 21–22).

Relator responds that Bayer and J&J have misunderstood his theory of fraud: His theory is not implied false certification but rather one of fraudulent inducement of the market—that they made "an initial false representation that the government relied upon to its detriment," thus "caus[ing] a domino effect throughout the market" and thereby causing "billions of dollars of fraudulently-gained government reimbursements." (Opp. Br. at 28). Relator contends that the Amended Complaint plausibly pleads that "Defendants omitted crucial safety information concerning Levaquin and Cipro side effects—as to the very existence of thes[e] effects, the severity, and their relative frequency." (*Id.*).

In reply, Bayer and J&J argue that Relator offers a new theory of fraud and should not be able to do so in opposition to their motions to dismiss. (J&J Reply at 7–8; Bayer Reply at 2). Moreover, they argue that Relator fails to plead his claim even under his new theory. (J&J Reply at 8–9; Bayer Reply at 3–6).

The Court agrees with Bayer and J&J on both of their rebuttal points. For one, the Amended Complaint clearly pursues a false certification theory—that "Defendants have, expressly and impliedly, falsely certified their compliance with these federal and state statutes and regulations." (Am. Compl. ¶ 148; *see also id.* ¶¶ 146–62). "[I]t is axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss." *Frederico v. Home Depot*, 507 F.3d 188, 201–02 (3d Cir. 2007) (quoting *Car Carriers, Inc. v. Ford Motor Co.*, 745 F.2d 1101, 1107 (7th Cir.1984)). Indeed, a court should "not consider after-the-fact allegations in

determining the sufficiency of [a] complaint under Rules 9(b) and 12(b)(6)." *Frederico v. Home Depot*, 507 F.3d 188, 202 (3d Cir. 2007). For another, the Amended Complaint contains hardly any facts suggesting that Bayer and J&J made misrepresentations of fact to, or withheld safety information from, the FDA.[3] At best, the Amended Complaint pleads that Bayer and J&J "fought the science" in two ways. (Am. Compl. ¶¶ 9, 54 & 59). First, at the November 5, 2015 FDA Advisory Committee meeting, when their representatives allegedly "vehemently denied both the connection between FQs, including Cipro, and the adverse reactions"; "went as far as to question whether FQAD was a real condition"; and "insisted the current labeling was sufficient." (*Id.* ¶ 59). Second, in response to requests for statements from the news media, Defendants allegedly "stood by the product." (*Id.* ¶ 54). However, these allegations are insufficient for several reasons.

First, the Amended Complaint fails to distinguish between Bayer and J&J—two distinct entities who sold different drugs and cannot be held accountable for the actions of each other.[4] Indeed, the Amended Complaint vaguely refers to statements of "Defendant" or "Defendants." Relator's allegations thus amount to an impressible group pleading—one that fails to meet even Rule 8(a)(2)'s notice pleading standard, let alone the particularity standard of Rule 9(b). *See Mensah v. Manning*, No. 18-9247, 2020 WL 91089, at *6 (D.N.J. Jan. 8, 2020) ("[T]o the extent Plaintiff seeks to lump several defendants together without setting forth what each particular defendant is alleged to have done, he has engaged in impermissibly vague group pleading." (quoting *Ingris v. Borough of Caldwell*, No. 14-0855, 2015 WL 3613499, at *5 (D.N.J. June 9,

[3] In light of this, the Court does not address whether a fraudulent inducement theory is viable in the absence of a contractual relationship. *See In re Plavix Mktg., Sales Prac. & Prod. Liab. Litig. (No. II)*, 332 F. Supp. 3d 927, 952 (D.N.J. 2017) ("In the absence of any binding or persuasive authority suggesting that a theory of liability formed in the context of contracts should be applied equally in the context of non-contract interactions with government regulatory bodies, as in this case, marketing statements to formulary committees, this Court will not craft a fraud-on-the-formulary theory for Relator out of whole cloth.").

[4] Relator claims that Bayer and J&J conspired to defraud the United States. (Am. Compl. ¶¶ 3 & 166; Opp. Br. at 5). But besides this bare legal conclusion, there are no facts in the Amended Complaint suggesting a conspiracy.

2015))). Bayer and J&J raised this point in their opening briefs (J&J Mov. Br. at 28; Bayer Mov. Br. at 20 n.9), and Relator failed to address it in opposition (*see* J&J Reply at 6).

Second, and similarly, the Amended Complaint fails to allege what Bayer and J&J actually said about Cipro, Levaquin, and the adverse effects of both. Under Rule 9(b), a relator alleging fraud must "support its allegations 'with all of the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where and how of the events at issue.'" *United States ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 307 (3d Cir. 2016) (quoting *In re Rockefeller Ctr. Props., Inc. Securities Litig.*, 311 F.3d 198, 217 (3d Cir. 2002)). However, Relator does not allege what false statements of fact Bayer and J&J made when they allegedly denied the connection between their products and the alleged side effects and instead stood by their products. *Cf. United States ex rel. Brown v. Pfizer, Inc.*, No. 05-6795, 2017 WL 1344365 (E.D. Pa. Apr. 12, 2017) (holding that the relator adequately pled falsity by citing exactly what the defendant misrepresented to, and withheld from, the FDA). Moreover, this information is not especially burdensome to uncover; what Bayer and J&J said to the FDA is public information, and in fact, Bayer and J&J filed the transcript of the relevant FDA meeting on this Court's docket. (D.E. No. 38-8, Ex. F; D.E. No. 41-8, Ex. F).

Third, Relator does not allege what specific information Bayer and J&J failed to disclose and why they were under a duty to disclose that information even though, as discussed below, the FDA was made aware of all the information put forth in the Amended Complaint. Indeed, the FCA "does not contain an independent duty to disclose certain information." *United States ex rel. Harman v. Trinity Indus. Inc.*, 872 F.3d 645, 667 n.90 (5th Cir. 2017) (citing 31 U.S.C. § 3729). Thus, "[t]here can only be liability under the False Claims Act where the defendant has an obligation to disclose omitted information." *Id.* (quoting *United States ex rel. Berge v. Bd. of*

Trustees of Univ. of Ala., 104 F.3d 1453, 1461 (4th Cir. 1997)). And ordinarily, a person is not under a duty to disclose information known to another person. *See* Restatement (Second) of Torts §§ 550, 551 (Oct. 2021). This is not to suggest Bayer and J&J were not under a duty to disclose—but it is to say the Amended Complaint does not specify whether and why they were under such a duty.

Because Relator fails to plead falsity, his FCA claim is dismissed.

B. Materiality

Nor has Relator sufficiently alleged materiality. The FCA defines materiality as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). The standard for materiality, the Supreme Court said in *Escobar*, is "rigorous" and "demanding." 579 U.S. at 192, 194; *see also Petratos*, 855 F.3d at 492 ("[W]e now join the many other federal courts that have recognized the heightened materiality standard . . . ."). The demanding standard ensures that the FCA "is not 'an all-purpose antifraud statute.'" *Escobar*, 579 U.S. at 194 (quoting *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 672 (2008)). Thus, a material misrepresentation or omission is not one that is minor or insubstantial or that concerns information that gives the Government the option to decline payment. *Id.* Instead, a material misrepresentation or omission concerns information "that goes 'to the very essence of the bargain.'" *Petratos*, 855 F.3d at 489 (quoting *Escobar*, 579 U.S. at 193 n.5). "Materiality may be found where 'the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement.'" *Id.* (quoting *Escobar*, 579 U.S. at 195). "On the other hand, it is 'very strong evidence' that a requirement is not material 'if the Government pays a particular claim in full

despite its actual knowledge that certain requirements were violated.'" *Id.* (quoting *Escobar*, 579 U.S. at 195); *accord Spay*, 875 F.3d at 764.

Bayer and J&J argue that the Amended Complaint fails to plausibly plead materiality. In particular, they argue that Relator fails to identify a statutory, regulatory, and contractual provision that they violated and that is material to the Centers for Medicare and Medicaid Services' ("CMS") decision to pay reimbursements. (J&J Mov. Br. at 23–28; Bayer Mov. Br. at 11–18). They also argue that materiality is lacking because, despite having full knowledge of the facts underlying Relator's proposed labeling changes, the FDA declined to order the changes and CMS continued to pay reimbursements. (J&J Mov. Br. at 26–28; Bayer Mov. Br. at 11–18). For this latter argument, Bayer and J&J rely largely on the Third Circuit's decision in *Petratos*. (J&J Mov. Br. at 26–28; Bayer Mov. Br. at 12).

In *Petratos*, the Third Circuit affirmed a district court's dismissal of a qui tam complaint for failure to plead materiality. 855 F.3d at 489. The relator there alleged that a medical device manufacturer suppressed safety data from the FDA, causing physicians to certify that a drug was reasonable and necessary for certain at-risk Medicare patients, and thus causing the CMS to reimburse claims for the drug. *Id.* at 485. However, there were no factual allegations that CMS would not have paid reimbursements for the drugs if the alleged reporting deficiencies were cured. *Id.* at 490. In fact, the relator "essentially concede[d] that CMS . . . consistently reimburse[d] . . . claims with full knowledge of the purported noncompliance." *Id.* Moreover, the relator had disclosed the fraud to the FDA and the FDA did not "initiate proceedings to enforce its adverse-event reporting rules or require [a] change [in the] label." *Id.*; *see also Spay*, 875 F.3d at 764 (holding there was no materiality where "CMS knew that dummy Prescriber IDs were being used by PBMs, that it routinely paid PBMs despite the use of these dummy Prescriber IDs, and that

CMS only 'signaled [a] change in position' well after 2007"). Finally, the Third Circuit found that the Government's decision not to intervene cut against materiality. *Petratos*, 855 F.3d at 490.

Relator responds that his "fraudulent inducement theory need not include an actual statutory, regulatory, or contract[ual] violation" because, he insists, he is not bringing an implied false certification claim but rather a fraudulent inducement claim. (Opp. Br. at 33). Thus, he need only plead (i) that Bayer's and J&J's "willful omissions and/or false certifications were material to the FDA's decisions on approval and labeling" and (ii) that "the FDA's labeling and authorizations were material to CMS and state counterparts' payment decisions." (*Id.*). Relator also argues that *Petratos* is distinguishable because the relator in *Petratos* conceded that the FDA declined to make labeling changes even after he shared all of the relevant information with the FDA. (*Id.* at 36). Meanwhile, here, the FDA made several changes in the labeling of Cipro and Levaquin after learning new information concerning the safety of both, and Bayer and J&J omitted certain safety information to the FDA, who was therefore not aware of all of the safety information. (*Id.* at 34–39).

In reply, Bayer and J&J argue that Relator does not identify any information that the FDA was unaware of. (J&J Reply at 9–10; Bayer Reply at 6–8). They also argue that Relator failed to respond to the fact that the FDA declined to change the label of Cipro and Levaquin in the manner urged by Relator, or the fact that the CMS continued to pay reimbursements despite knowledge of the alleged safety concerns. (J&J Reply at 10; Bayer Reply at 7–10).

The Court agrees with Bayer and J&J. For starters, the Court again disagrees with Relator that he is bringing anything other than an implied false certification theory of fraud. That theory requires him to plead Bayer and J&J failed to comply with a material statutory, regulatory, or

contractual requirement. Without identifying what Bayer and J&J failed to comply with, Relator clearly cannot satisfy materiality.

Moreover, even under Relator's proposed framework, he does not plausibly plead materiality. The Amended Complaint does not identify any information concerning the safety of Cipro and Levaquin that the FDA was unaware of. The Amended Complaint relies on (i) the FDA's pharmacovigilance review of systemic FQ exposure dated April 17, 2013 (Amended Compl. ¶¶ 7, 51, 57–58 & 67–68); (ii) FAERS data, which is reported to the FDA (*id.* ¶¶ 81–82, 101, 103–04, 113 & 123–26); (iii) Relator's own citizen petitions submitted to the FDA on June 18, 2014, and September 8, 2014 (*id.* ¶¶ 50–51 & 57); (iv) Relator's analysis of patient data that he submitted to the FDA on November 5, 2015, at the FDA Joint Meeting of the Antimicrobial Drugs Advisory Committee and Drug Safety and Risk Management Advisory Committee (*id.* ¶¶ 58–59); (v) an FDA briefing document for the November 5, 2015 meeting (*id.* ¶¶ 75 & 89); and (vi) his study, published in January or February 2016, that "combined a clinical study of 94 patients with an experiment utilizing C57BL/Mice" (*id.* ¶ 132; *see also id.* ¶¶ 56, 62, 133, 135 & 137). With the exception of Relator's clinical study on mice, the Amended Complaint confirms that the FDA was aware of all the other safety information concerning Cipro and Levaquin because that information was either in an FDA document or presented to the FDA. And while the Amended Complaint does not explicitly state that the FDA was aware of Relator's clinical study on mice, the Amended Complaint does not say the FDA was unaware of the study. Moreover, the transcript of the FDA's November 5, 2015 meeting, which Relator relies upon in his Amended Complaint, confirms that he presented some of his findings to the FDA. (D.E. No. 38-8, Ex. F, at 218–19; D.E. No. 41-8, Ex. F, at 218–19). *See Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014) (explaining that a court may take judicial notice of public records, which includes "materials like

decision letters of government agencies and published reports of administrative bodies"); *In re Incyte S'holder Litig.*, No. 13-0365, 2014 WL 707207, at *5 n.6 (D. Del. Feb. 21, 2014) (considering, on a Rule 12(b)(6) motion, "various Incyte SEC filings, press releases, and transcripts of the conference calls" because "Plaintiff does not oppose Defendants' request for judicial notice, and because Plaintiff's Complaint refers to and quotes extensively from many of these documents").

Relator purports that the FDA was unaware of the potential safety issues of Cipro and Levaquin, but he fails to so allege with the requisite specificity. (*See* Opp. Br. at 32–39). Nor does he cite anything in the Amended Complaint suggesting there was safety information that was unknown to the FDA. (*Id.*). Notably, Relator appears to concede the opposite—that he and "the *FDA's own scientists* uncovered the *full extent* of FQ side effects." (*Id.* at 2 (emphasis added)). This case thus stands almost on all fours with *Petratos*: (i) the FDA was aware of all the safety information concerning both drugs; (ii) the FDA declined to change the label as Relator would like; (iii) CMS continued to pay reimbursements; and (iv) the Government declined to intervene in the qui tam action. *See* 855 F.3d at 490.

To be sure, unlike *Petratos*, there are allegations here suggesting that the FDA made labeling changes as a result of new safety information about Cipro and Levaquin. But under the circumstances, that fact cuts further against materiality. The FDA made those labeling changes *based on the same information* that Bayer and J&J allegedly failed to disclose—yet the FDA conspicuously declined to include the side effects that Relator faults Bayer and J&J for not including. Said another way, the FDA, with all the information alleged in the Amended Complaint, appears to have made a conscious decision not to include certain side effects in the labels for Cipro and Levaquin. Thus, while the FDA's changes "show that the FDA was paying attention," the

"lack of any further action also shows that the FDA viewed the information, including that furnished by Relator[], differently than Relator[] do[es]." *United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29 (1st Cir. 2017); *see also D'Agostino v. ev3, Inc.*, 845 F.3d 1, 8 (1st Cir. 2016) ("The FDA's failure actually to withdraw its approval of Onyx in the face of D'Agostino's allegations precludes D'Agostino from resting his claims on a contention that the FDA's approval was fraudulently obtained."); *Plavix*, 332 F. Supp. 3d at 959 (looking at "the regulatory agency's real-world conduct"). "To rule otherwise would be to turn the FCA into a tool with which a jury of six people could retroactively eliminate the value of FDA approval and effectively require that a product largely be withdrawn from the market even when the FDA itself sees no reason to do so." *D'Agostino*, 845 F.3d at 8. "The FCA exists to protect the government from paying fraudulent claims, not to second-guess agencies' judgments about whether to rescind regulatory rulings." *Id.*

The cases cited by Relator do not lead to a contrary conclusion. (Opp. Br. at 34–36). In *Brown*, 2017 WL 1344365, the court found materiality because there was no suggestion that the Government had actual knowledge of the defendant's misrepresentations to the FDA, and because the relator alleged that the defendant, among other things, misrepresented the results of a study and supported the publication of ghost written articles that misrepresented the results of the same misrepresented study. *Id.* at *10–11. In *United States v. Honeywell Int'l Inc.*, 502 F. Supp. 3d 427 (D.D.C. 2020), the court denied summary judgment as to materiality because the Government presented "specific evidence" demonstrating that the defendant "sent 'bad' data" to obtain a Government contract, *id.* at 455, and there was a "substantial factual dispute as to whether the government had 'full knowledge of the purported noncompliance,'" *id.* at 459 (quoting *Petratos*, 855 F.3d at 489). In *United States ex rel. Campie v. Gilead Sciences, Inc.*, 862 F.3d 890 (9th Cir.

2017), the Ninth Circuit found materiality was sufficiently alleged because "the parties dispute exactly what the government knew and when, calling into question its 'actual knowledge.'" *Id.* at 906–07. Acknowledging that materiality may not be present if "the government regularly pays this particular type of claim in full despite actual knowledge that certain requirements were violated," *Campie* explained that "such evidence is not before us." *Id.* at 907. Finally, in *Nargol*, 865 F.3d 29, the First Circuit found that a relator sufficiently pled an FCA claim premised on the defendant selling palmed off latently defective versions of its FDA-approved product. *Id.* at 37–41. The court explained that there was no indication that the Government was unaware of the defendant's non-compliance, and that doctors had no reason to know the product sold to them was not the FDA-approved version. *Id.* at 41.

Nargol's other holding, in fact, affirmatively supports the Court's holding here. *Nargol* affirmed dismissal of the relators' other FCA claim premised on a fraud-on-the-FDA theory for failure to plead materiality. *Id.* at 35. Like here, the complaint in *Nargol* "allege[d] that Relators told the FDA about every aspect of the design of the Pinnacle MoM device that they felt was substandard, yet the FDA allowed the device to remain on the market." *Id.* Additionally, the court noted that, even though there was some level of regulatory enforcement by the FDA, "the lack of any further action also shows that the FDA viewed the information, including that furnished by Relators, differently than Relators do." *Id.*

Relator argues that the Court may infer materiality by the fact that Bayer and J&J took "active steps to coverup its noncompliance and/or other fraudulent conduct." (Opp. Br. at 33). As one court has explained, a defendant's "elaborate cover-up suggest[s] that the [defendant] realize[s] the materiality of" a condition for payment. *United States v. Triple Canopy, Inc.*, 857 F.3d 174, 176 (4th Cir. 2017). However, contrary to Relator's argument, nothing in the Amended

Complaint suggests that Defendants "willful[l]y suppress[ed] . . . its own findings." (Opp. Br. at 34).

Accordingly, Relator fails to plead materiality.[5]

C. Off-Label Use

The Amended Complaint also asserts allegations concerning J&J promoting off-label use of Levaquin. (Am. Compl. ¶¶ 13, 15, 42–43, 95–100 & 121). However, as J&J points out, those allegations are conclusory at best. (J&J Mov. Br. at 22–23). Relator claims that J&J knowingly failed to condemn past and prevent future off-label use and that one J&J employee promoted off-label use. (Am. Compl. ¶¶ 96, 98 & 100). But he offers little more than that. He does not allege "the who, what, when, where and how of the events at issue.'" *Moore & Co., P.A.*, 812 F.3d at 307 (quoting *Rockefeller Ctr.*, 311 F.3d at 217). And he offers little on how the alleged off-label use constitutes fraud against the United States. Relator thus fails to satisfy Rule 9(b)'s particularity requirement.

D. State Law Claims

Relator also brings various claims under analogous state false claims statutes. (Am. Compl. ¶¶ 168–318). Bayer and J&J argue that those claims should be dismissed because they rise and fall with the federal FCA claim. (J&J Mov. Br. at 8 n.4; Bayer Mov. Br. at 30 n.13). Relator argues that Bayer and J&J have incorrectly assumed that all of his state law claims follow the FCA's materiality standard and, therefore, have not offered an appropriate basis for dismissal. (Opp. Br. at 44–48). However, the Court also dismisses the FCA claim for failure to plead falsity.

[5] In light of the Court's holding, the Court does not address whether a relator may satisfy materiality indirectly—i.e., by showing that a defendant's fraud was material to the FDA's labeling decision and that the FDA's labeling decision was material to CMS's decision to pay, as opposed to more directly showing that the defendant's fraud on the FDA was material to CMS's decision to pay. *Cf. Petratos*, 855 F.3d at 492 (rejecting "restyled causation arguments as proof of materiality").

In any event, Relator invokes jurisdiction over these state law claims pursuant to 31 U.S.C. § 3732(b). (Am. Compl. ¶ 17). That section provides, "[t]he district courts shall have jurisdiction over any action brought under the laws of any State for the recovery of funds paid by a State or local government if the action arises from the same transaction or occurrence as an action brought under section 3730." § 3732(b). There now being no FCA claim brought on the behalf of the United States, the Court declines to exercise supplemental jurisdiction over the state law claims. *See United States ex rel. Mohajer v. Omnicare, Inc.*, 525 F. Supp. 3d 447, 461 (S.D.N.Y. 2021); *United States ex rel. LaFauci v. AbbVie Inc.*, No. 15-7931, 2019 WL 1450791, at *5 (D.N.J. Apr. 2, 2019).

IV. CONCLUSION

Based on the foregoing, Bayer's and J&J's motions (D.E. Nos. 38 & 41) are GRANTED. The Amended Complaint is dismissed *without prejudice*. An appropriate Order follows.

Date: March 31, 2022

Hon. Esther Salas, U.S.D.J.